

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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SANOFI-SYNTHELABO, SANOFI-SYNTHELABO INC.,
and BRISTOL-MYERS SQUIBB SANOFI
PHARMACEUTICALS HOLDING PARTNERSHIP,

Plaintiffs,

- against -

APOTEX INC. and APOTEX CORP.,

Defendants.
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02 Civ. 2255 (RWS)

O P I N I O N

A P P E A R A N C E S:

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Sweet, D.J.,

The defendants Apotex, Inc. and Apotex Corp. (collectively, "Apotex") have moved pursuant to Rules 37(a)(2) and 37(a)(3) of the Federal Rules of Civil Procedure to compel plaintiffs Sanofi-Synthelabo, Sanofi-Synthelabo Inc. and Bristol-Myers Squibb Sanofi Pharmaceuticals Holding Partnership (collectively, "Sanofi") to (1) produce all correspondence after November 4, 1988, in unredacted form, bearing on the subject matter of why Sanofi decided to cancel original claims 6-9 in the prosecution of patent application 07/155,550, which matured into U.S. Patent 4,847,265 (the "'265 Patent") on July 11, 1989, and (2) provide deposition testimony on this subject matter.

For the reasons set forth below, the motion is granted.

Prior Proceedings

Apotex has filed affirmative defenses and counterclaims, alleging that the '265 patent is invalid for lack of novelty (35 U.S.C. § 105), obviousness (35 U.S.C. § 103), and incorrect naming of inventors (35 U.S.C. § 105(f)), and that it is also unenforceable due to inequitable conduct in the prosecution of the '265 patent.

Discovery has proceeded with voluminous document production by all parties and numerous depositions.

The application for the '265 patent was filed in the United States on February 12, 1988, having an earlier foreign application priority date. On November 4, 1988, the patent examiner rejected all 11 original claims pending in the application. Original claims 6-9 were process claims. In its amendment dated January 9, 1989, Sanofi cancelled process claims 6-9. However, foreign counterpart patents to the '265 patent contain process claims. During the deposition of Sanofi's Rule 30(b)(6) witness on the prosecution of the '265 patent, Michael Alexander, Ph.D., Esq. ("Alexander"), Apotex inquired into the reasons why Sanofi cancelled process claims 6-9.

Alexander testified that the reason Sanofi cancelled claims 6-9 in the patent application in the United States after the first office action was "to expedite prosecution," that the source of this information was Peter Varady ("Varady"), an employee of Cabinet Lavoix, Sanofi's outside European attorneys and agent, at the relevant time who was the principal person in charge of liaison between Sanofi and its United States patent counsel with regard to application No. 07/155,550.

Varady testified in his September 11, 12, 2003 deposition that he is a chemical engineer and European patent attorney

registered to practice before the European Patent Office ("EPO"), that he worked for Cabinet Lavoix in Paris from 1983 to December 1992, that Cabinet Lavoix serviced patent prosecutions for Sanofi during that time period in Europe and around the world, and that Varady was involved in filing the priority patent applications in France for Sanofi on which the '265 patent is based. Those priority applications were FR 87 02025, filed February 17, 1987, and FR 87 16516, filed November 27, 1987.

Application No. 07/155,550 (the "'550 application") was filed in the United States on February 12, 1988, and claimed priority to FR 87 02025 and FR 87 16516. The American attorneys who filed the '550 application were Wegner & Bretschnieder of Washington, DC. Varady dealt directly with Wegner & Bretschnieder, and with the Sanofi patent department, especially Sanofi patent attorney Jacqueline Laforest, who was one of the persons in charge in 1987. The Sanofi patent department did not directly deal with Wegner & Bretschnieder and Cabinet Lavoix and Varady served as liaison for Sanofi patent prosecutions in the United States and other jurisdictions, including Canada, the EPO, Norway, and other countries. Varady worked on the filing of Sanofi's patent applications claiming priority to FR 87 02025 and FR 87 16516 with patent counsel in those other nations and jurisdictions. Varady and Cabinet Lavoix took direction from Sanofi's patent department and then communicated instructions to patent counsel in jurisdictions outside France.

During Varady's deposition, Sanofi counsel, Mr. Solander, instructed Varady not to answer numerous questions on grounds of attorney-client privilege and cautioned the witness simply to answer numerous questions "yes" or "no" and not to reveal the substance of any communications between himself and the Sanofi patent department or between himself and American patent counsel.

On September 25 and 26, 2003, Alexander testified as Sanofi's Rule 30(b)(6) witness on numerous topics, including topic 5 in the deposition notice which reads: "5. The amendment dated January 9, 1989 filed in connection with Application No. 07/155,550, signed by attorney Helmuth Wegner, Reg. No. 17,033." Alexander testified as follows:

Q: In Exhibit 211 [USPTO Office Action dated November 4, 1988], let me direct your attention to page S 91231. This is the page that is marked no. 3 in the office action and about the middle of the page, do you see the sentence claim 6 to 9 are rejected under 35 U.S. Code 103 as being unpatentable over Fieser et al [textbook entitled Advanced Organic Chemistry, pp. 85-88, 1961] and Aubert et al. [prior art U.S. Patent 4,529,596]?

A: Yes.

Q: In the following several paragraphs does the examiner there explain the obviousness rejection that he made?

A: Yes.

Q: What is the reason Sanofi did not traverse this rejection.

SOLANDER: I will caution you not to reveal communications between Sanofi and its lawyers.

A: Based on the conversation I had with Mr. Varady concerning this case, he said that simply to expedite prosecution, claims 6 to 9 were cancelled.

Q: Is that the sole reason?

A: That's the only reason obtained during my investigation.

. . .

Q: Are claims 6 to 9 process claims?

A: Yes.

(See Deposition Transcript of Michael Alexander at 168:21-170:13.

Q: Who at Sanofi made the decision to cancel claims 6 through 9?

A: I don't know.

(See Deposition Transcript of Alexander at 174:11-13.

Later in his deposition, Alexander testified that he did not know if any other reason contributed to the decision to cancel claims 6-9, or whether the text of the Fieser textbook contributed to the decision. (See Deposition Transcript of Alexander at 207:1-208:25). Then Alexander testified as follows:

Q: Is it correct, Dr. Alexander, that the new drug application for clopidogrel was still years away from being ready in November and December of 1998 and January 1989?

SOLANDER: Objection to form, outside the scope.

A: I didn't investigate this in preparation for this.

Q: Could you tell me why it was important to expedite prosecution of the application in the U.S. in 1988 and 1989?

A: I don't know.

(See Deposition Transcript of Alexander at 209;;9-21).

On April 11, 1991, the EPO examining division rejected Sanofi's European Patent application based on FR 87 02025 and FR 87 16516 for lack of novelty and lack of invention. All claims were rejected. Sanofi decided to appeal. Sanofi's appeal brief to the EPO Board of Appeal was filed by Varady on August 20, 1991. Alexander testified as follows about Sanofi's appeal brief:

Q: Is it true that Mr. Varady's appeal brief asked for allowance of the process claims as well as the composition of matter claims, is that correct.

A: It appears there are process claims in the appeal, yes.

Q: Can you tell me why Sanofi would appeal process claims in Europe but not appeal them in the United States?

A: I don't know, perhaps the business considerations were different than in the U.S.

Q: Is that just rank speculation on your part or do you have any information at all?

A: No, I just said perhaps. I have no information one way or the other.

Q: Mr. Alexander, what are the business reasons that Sanofi appealed the process claims in Europe but allowed the cancellation of the process claims in the United States?

A: I don't know.

Q: Is the market for clopidogrel in the United States negligible compared to Europe?

SOLANDER: Objection to form, beyond the scope.

A: I don't know.

(See Deposition Transcript of Alexander at 271:20-273:8).

During the course of Alexander's deposition, Apotex's counsel requested all documents constituting communications regarding Sanofi's response to the November 4, 1988 Office Action on the basis that Sanofi waived the attorney-client privilege, but Sanofi's counsel refused.

This motion followed and was heard and marked fully submitted on October 29, 2003.

The Relevance of the Privileged Information

Original claims 6-9 concern process claims which are present in the Canadian counterpart of the '265 patent. Apotex notes that a process claim is also present in the European counterpart patent. Apotex seeks to discover why Sanofi did not pursue original process claims 6-9 when the counterpart patents in other countries contain process claims. Apotex has challenged Sanofi's explanation that it was a "business reason" to drop process claims 6-9 because Sanofi's NDA for Plavix (which allegedly is covered by the '265 patent) was not filed until several years

later on April 28, 1997 and because it was Sanofi's attorney, Mr. Solander, not the Rule 30(b)(6) witness, who injected the words "business reason" behind the reasons why Sanofi cancelled claims 6-9. The Rule 30(b)(6) witness, Alexander, could not answer why it was important to expedite prosecution in the U.S., or provide any of the "business reasons" for cancelling claims 6-9 in the U.S.

According to Apotex, through the disclosure of one underlying reason for the cancellation of claims 6-9, Alexander, Sanofi's Rule 30(b)(6) witness on patent prosecution, waived Sanofi's privilege with respect to all documents and testimony relating to the cancellation of original claims 6-9.

Although this is an action appealable to the Court of Appeals for the Federal Circuit, Second Circuit law applies to the applicability and waiver of the attorney-client privilege. In re Pioneer Hi-Bred Intern., Inc., 238 F.3d 1370, 1374 (Fed.Cir. 2001). Under Second Circuit law, the attorney-client privilege attaches when:

(1) where legal advice of any kind is sought (2) from a professional legal advisor in his capacity as such, (3) the communications relating to that purpose, (4) made in confidence (5) by the client, (6) are at his instance permanently protected (7) from disclosure by himself or by the legal advisor, (8) except the protection be waived ...

In re Grand Jury Subpoena Duces Tecum Dated September 15, 1983, 731 F.2d 1032, 1036 (2d Cir. 1984) (holding that tax advice was legal advice, not business advice), citing United States v. Bein, 728 F.2d 107, 112 (2d Cir. 1984). Communications relating to the prosecution of a patent application are considered to be seeking legal advice or services despite the fact that such communications might contain other information that is tangential to the legal services involved with patent prosecution. In re Spalding Sports Worldwide, Inc., 203 F.3d 800, 805-06 (Fed.Cir. 2000). All aspects of patent prosecution; that is, from patentability determinations to drafting patent applications to amending patent applications, have been held to constitute the practice of law. Sperry v. State of Florida ex rel. The Florida Bar, 373 U.S. 379, 383 (1963).

Sanofi's January 9, 1989 amendment cancelling original claims 6-9 constituted the practice of law and communications relating to such amendment sought legal advice or services. The communications disclosed by Sanofi's Rule 30(b)(6) witness about why original claims 6-9 were cancelled were the instructions given by Sanofi to the legal professionals at Cabinet Lavoix in response to the November 4, 1988 Office Action. The redaction and/or withholding of documents containing communications about why Sanofi cancelled claims 6-9 show the confidential nature of such communications and that Sanofi does not wish to disclose the same.

The communications relating to cancelling claims 6-9 was clearly a "privileged communication." The communication was privileged in that it: (1) sought legal services in the amendment of patent claims; (2) was from Varady, a European patent attorney (see Alexander Dep. at 168-70, Exh. G); (3) the reason for the amendment clearly related to the legal services of amending the patent claims; (4) was made in confidence as evidenced by redactions and withheld documents; (5) was made by Sanofi to Cabinet Lavoix; (6) was maintained in confidence until Alexander's deposition; (7) was not disclosed by Sanofi and/or his attorneys, until the disclosure by Alexander, Sanofi's Rule 30(b)(6) witness on patent prosecution. The communications disclosed by Alexander was subject to the attorney-client privilege and as a step in the patent application process, relevant to the issues before the court.

Sanofi Has Forfeited The Privilege

Sanofi has provided only a portion of the reasoning behind the cancellation of claims 6-9 and as such has sought to use the attorney-client privilege as a sword and a shield at the same time. Bank Brussels Lambert v. Credit Lyonnaise (Suisse), 1995 WL 598971 at *5 (S.D.N.Y. 1995), citing In re von Bulow, 828 F.2d 94, 103 (2d Cir. 1987).

John Doe Co. v. United States, 350 F.3d 299 (2d Cir. 2003) has clarified the terminology and the reasoning behind the determinations relating to the attorney-client privilege and its waiver, forfeiture, implied waiver and at issue waiver.

[2] Forfeiture of this nature is justified by considerations of fairness to the adversary. In some circumstances, courts have rules that it would be unfair for a party asserting contentions to an adjudicating authority to then rely on its privileges to deprive its adversary of access to material that might disprove or undermine the party's contentions. While we have sometimes used broad language in describing the doctrine, such as generalizing about the incompatibility of using the assertions as a "sword" while using privileges attaching to related matter as a "shield," because the doctrine is rooted in fairness we have also cautioned against broad generalizations, stressing that "[w]hether fairness requires disclosure ... is best decided on a case by case basis, and depends primarily on the specific context in which the privilege is asserted." In re Grand Jury, 219 F.3d at 183.

* * *

The unfairness courts have found which justified imposing involuntary forfeiture generally resulted from a party's advancing a claim to a court or jury (or perhaps another type of decision maker) while relying on its privilege to withhold from a litigation adversary materials that the adversary might need to effectively contest or impeach the claim. In United States v. Nobles, for example, the defendant in a criminal trial wished to call to the stand an investigator who on the defendant's behalf had interviewed the prosecutor's principal incriminating witnesses. 422 U.S. at 229. The defendant intended to elicit from the investigator that the prosecution witnesses had made statements to him which substantially undermined their credibility in identifying the defendant as the perpetrator of the crime. The investigator had prepared a report of the interviews. The prosecutor demanded that the report be produced; the defendant refused to produce it on grounds of work-product privilege. The trial court ruled, and the Supreme Court agreed, that if the investigator was to be called as a defense witness, testifying to the jury about his interviews of the prosecution witnesses, the defendant's

privilege with respect to the investigator's report about those interviews would be forfeited and the report would be ordered produced to the prosecutor. It would be unfair to the prosecutor to allow the defendant to present this testimony to the jury without giving the prosecutor access to a report which might effectively impeach it. See Nobles, 42 U.S. at 239-40.

*4 Our court reached a very similar conclusion in Bilzerian, 926 F.2d 1285. The defendant in a criminal securities trial sought a pretrial ruling that his attorney-client privilege would remain intact, shielding the advice he had received from his attorneys, notwithstanding testimony he proposed to give that he did not willfully violate the securities laws because he believed his actions were consistent with law. The trial court ruled, and we agreed, that if the defendant gave testimony asserting to the jury his belief in the lawfulness of his actions, fairness would require that the prosecutor have access to the advice he in fact received from his attorneys because this evidence might impeach his claim of innocent state of mind.

Unfairness was crucial to both rulings: In the courts' perception, it would be unfair to force the prosecutor to run the risk that the jury would accept the defendant's claims as to the facts the defendant put in issue while allowing the defendant, by assertion of his privileges, to deny the prosecutor access to directly pertinent material that might effectively impeach the defendant's claims.

Id. at 302-03.

Here the unfairness results from a partial explanation, believed by Apotex to be possibly false, for an action relating to the patent at issue when a complete explanation according to Apotex would be relevant to the validity of the patent.

Because the partial representation -- the so-called "business advice" -- is made to the Court in the context of a

patent application process and because the privileged information may bear on the validity of the patent at issue, the attorney-client privilege has been forfeited.

Settle order on notice.

It is so ordered.

New York, NY
January 26, 2004

ROBERT W. SWEET
U.S.D.J.